DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

April 3, 2015

Ivoclar Vivadent, Inc.
Ms. Donna Marie Hartnett
Director, QA/Regulatory Affairs
175 Pineview Drive
Amherst, New York 14228

Re: K143575
Trade/Device Name: Accu-Dent® XD
Regulation Number: 21 CFR 872.3660
Regulation Name: Impression material
Regulatory Class: II
Product Code: ELW
Dated: January 2, 2015
Received: January 5, 2015

Dear Ms. Hartnett:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Erin I. Keith, M.S.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K143575

Device Name: Accu-Dent® XD

Indications For Use:

The Accu-Dent XD impression materials are recommended for used to create highly detailed impressions of the hard and soft tissues of the oral cavity includin the following list of indications:

- Complete and partial denture impressions
- Opposing models for fixed and removable prosthesis
- Study Model
- Temporary crown & Bridge impressions
- Whitening Trays
- Mouth Guards
- Orthodontic Impressions

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

510(K) SUMMARY

Accu-Dent XD

Revised April 3, 2015

Contact: Donna Marie Hartnett

Company: Ivoclar Vivadent, Inc.
175 Pineview Drive, Amherst, NY 14228
800-533-6825

Date Prepared: April 3, 2015

Proprietary Name: **Accu-Dent® XD**

Classification Name: Material, Impression (872.3660)
(Classification Code ELW)

Predicate Device: Tropicalgin (K043131) & Neocolloid (K981091) by Zhermack sPA

Device Description: Accu-Dent XD is a two-part Alginate impression system intended to be placed on a preformed impression tray and used to reproduce the structure of a patient's teeth and gums. The device is intended to provide impressions models for study and for production of restorative prosthetic devices, such as full and partial dentures.

Intended Use:

The Accu-Dent XD impression materials are recommended for use to create highly detailed impressions of the hard and soft tissues of the oral cavity including the following list of indications:

- Complete and partial denture impressions
- Opposing models for fixed and removable prosthesis
- Study Model
- Temporary crown & Bridge impressions
- Whitening Trays
- Mouth Guards
- Orthodontic Impressions

Comparison to Predicate: The predicate device to which Accu-Dent XD has been compared is Tropicalgin (K043131) & Neocolloid (K981091) by Zhermack sPA . Accu-Dent XD consists of a tray material (comparable to Tropicalgin) and a Syringe material (comparable to Neocolloid) which, when used together are intended to take impressions of the oral cavity. The materials have been compared based on physical properties for working time, setting time, strain in compression, recovery from deformation, tear strength, gypsum compatibility and detail reproduction. Accu-Dent XD materials have been determined to be substantially equivalent to the predicate device.

Indications	(Tropicalgin) Dental impression material intended to be placed on a preformed impression tray and used to reproduce the structure of a patient's teeth. It is also intended to provide models for study and for production of restorative prosthetic devices, such as dental inlays and dentures. (Neocolloid) Alginate dental impression materials that are intended to be used to make dental impressions. The resulting impressions are used to make plaster models of then teeth.	The AccuDent XD impression materials are recommended for use to create highly detailed impressions of the hard and soft tissues of the oral cavity including the following list of indications: • Complete and partial denture impressions • Opposing models for fixed and removable prosthesis • Study Models • Temporary crown & bridge impressions • Whiting Trays • Mouth Guards • Orthodontic Impressions
Discussion The variation is not substantial and is a refinement and clarification of the predicate's more general statement of indications.		

510(K) SUMMARY

Accu-Dent XD

Revised April 3, 2015

Technology		
	Predicate device	*Accu-Dent XD*
Working principle	Neocolloid and Tropicalgin were developed separately. The powder is intended to be mixed with water 18 gm powder to 36 ml water for Tropicalgin 18 gm powder to 36 ml water for Neocolloid The mixed paste is loaded onto a preformed perforated impression tray and inserted into the mouth. While in the mouth, the paste polymerizes so when it is removed, it leaves an impression of the patitent's dentition. Tropicalgin was designed to exhibit a chromatic color change as the materials set.	Accu-Dent XD Tray and Syringe materials were developed to work together. The powder is intended to be mixed with water 24gm gm powder to 44 ml water for Tray 9gm powder to 21 m water for Syringe The mixed syringe paste is loaded into a plastic delivery syringe with specially designed application tip and the material is dispensed directly onto the oral tissue by hand. The mixed tray paste is loaded onto a preformed perforated impression tray and inserted into the mouth. While in the mouth, the paste polymerizes so when it is removed, it leaves an impression of the patient's dentition. Accu-Dent XD also has the chromatic color change (Tray material only) as the materials set.
Discussion: The change in powder/water ratio has a minor impact on the physical properties of the device which is discussed below. The two-step clinical procedure has only impact on the finished impression. The color contrast provides for improved impression reading.		

Delivery forms	Neocolloid and Tropicalgin are delivered in bulk bags (500g and 453g respectively) which are scooped out by the user using a measuring spoon. Tropicalgin is Yellow and has a Mango scent Neocolloid is Orange and has an herbal scent	Accu-Dent XD Tray and Syringe Powers are delivered in single dose sealed pouches, 12 packages per box. Accu-Dent XD Tray is Blue Accu-Dent XD Syringe is Orange Both materials will have a mild mint scent
Discussion: Variations in color and scent play no active role in the performance of the materials. The new pre-dosed pouches are similar to the existing Accu-Dent materials, which have been on the market since before 1976. The packaging processes have been validated to assure adherence to the dosing specification		
Storage conditions	5-27 °C/41-80 °F for all items. 3 year shelf life	5-27 °C/41-80 °F for all items. 3-year shelf life
Discussion: No difference		
Principles of operation	Mix materials Load into preformed tray Insert into mouth and wait til set Remove from mouth Disinfect Pour the impression – dental stone	Mix materials Load Tray material into preformed tray Load syringe material into dispensing syringe Syringe material onto tissue Insert filled tray into mouth and wait until set Remove from mouth Disinfect Pour the impression – dental stone
Discussion: No variation except that the Tray and Syringe materials are intended to be used together. The predicate materials were intended to be used alone. The tray and syringe materials have been tested to work together. Once inserted into the mouth, they adhere together and pose no additional safety or efficacy issues.		

510(K) SUMMARY

Accu-Dent XD

Revised April 3, 2015

Technological Characteristics:

Conformity to product-specific Standard	*Predicate Device*	*Accu-Dent XD*
Applicable standard	ADA Spec 18/ ISO 1563	ISO 21563:2013 Dentistry: Hydrocolloid Impression Materials
Applicable FDA Guidance	Dental Impression Materials 1998	Dental Impression Materials 1998
Discussion ISO 21563 is a consolidation of 3 standards relating to impression materials including ISO 1563:1990 for Alginate impression materials. Under the new standard, the alginate materials are now required to be subject to the same tear strength test that has been in effect for the agar hydrocolloid impression materials (ISO 1564 and ISO 13716) instead of being subject to a compressive strength. This is understood to be a better performance measure.		

		Predicate Device			*Accu-Dent XD*	
Characteristic		Troplicalgin	Neocolloid		Tray	Syringe
Mixing Time		45”	45”		45”	45”
Working Time		1’35”	2’00”		1’15”	2’00”
Setting Time		2’35”	3’30”		2’30”	3’30”
Time in Mouth		1’00”	1’30”		30”	45”
Ratio Powder/Water		18gm 36ml	18gm 36ml		24gm 44ml	9gm 21ml
Compressive Strength	ISO 1563: 1990	1.362 N/mm	.916 N/mm	ISO 1563:1990	1.336 N/mm	.943 N/mm
Tear Strength	ISO 21563: 2013	0.647 N/mm	0.597 N/mm	ISO 21563:2013 0.38 N/mm(min)	0.778 N/mm	0.504 N/mm
Strain in Compression Permanent deformation	ISO 1563: 1990 5.0% - 20.0%	11.5%	10.3%	ISO 21563:2013 5.0% - 20.0%	10.0%	14.62%

Recovery from deformation	ISO 1563: 1990 Min. 95.0%	99%	99%	ISO 21563:2013 Min 95.0%	95.56%	97.63%
Gypsum Compatibility	ISO 1563: 1990 Line reprod 50 µm	complies	complies	ISO 21563:2013 Line reprod 50 µm	Complies	complies
Discussion: The primary change from the predicate is the powder/water ratio for the mixed alginate. This change impacts the physical properties, but not in a significant manner. The most notable change is the difference in the Recovery from deformation results. Although lower, the result remains within the acceptance criteria of the ISO 21563 and ISO 1563 of minimum 95%. Therefore, there is no expectation that the clinical outcome of the impression or the ultimate restoration will be affected.						

Guidance Document: This submission follow the requirements set out in FDA Guidance Document entitled Dental Impression Materials – Premarket Notification dated August 17, 1998.

CONCLUSION: The above data and analysis demonstrates that Accu-Dent XD is substantially equivalent to the predicate device.